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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,541	07/02/2001	Alan Houghton	MSK.P-012-2	3286
21121	7590	10/21/2003	[REDACTED]	[REDACTED] EXAMINER LI, QIAN J
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			[REDACTED]	[REDACTED] ART UNIT 1632 PAPER NUMBER

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/898,541	HOUGHTON ET AL.
	Examiner Q. Janice Li	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 July 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 July 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 21-24 are pending in the application and under current examination.

Priority

This application is a continuation of U.S. Application 09/230,199, now U.S. patent 6,294,378, a 371 application of PCT/US97/12675, and claims the benefit of priority from U.S. provisional application 60/022,710, filed 7/26/1996.

Specification

The specification contains sequence disclosures (figure 1) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) but are not present in the Sequence Listing and/or identified in the specification by sequence identifier numbers. Applicant must provide sequence identifiers, in the case that these sequences are not included in the original sequence submission, a paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office Action must include a complete response to the requirement for a Sequence Listing.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15-18, 21, and 24-27 of U.S. Patent No. 6,294,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are obvious variants over the composition, methods of making and using the composition claims of the cited patent.

Claims of the instant application and the cited patent are each drawn to a nucleic acid construct comprising an antigen-coding region and a sorting signal region encoding a protein which acts as a sorting signal to direct intracellular transport of the antigenic protein into the endosomes or the endoplasmic reticulum of a cell.

The claims of the present application and the cited patent differ one from the other in the claim language, wherein different terms or phrase such as "vaccine" or "composition" or "for genetic immunization" are used to define the

nucleic acid construct. However, the terms and phrase are art-known alternatives for describing a nucleic acid construct that serves as a genetic vaccine. As to the methods of making and using the composition in claims of the cited patent, there is no unobvious step in the processes, and the method of inducing an immune response flows directly from the intended use recitation in the preamble of instant claims 21-24.

Accordingly, the claimed nucleic acid in the copending and the present application are obvious variants. Therefore, the inventions as claimed are co-extensive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are vague and indefinite because the antecedent basis of claim recitation, "the protein or peptide" in line 6 of claim 21 is unclear in the context of the claim. This is because "an antigenic protein or peptide" appears in line 3 of claim 21, and "a sorting signal encoding a protein or peptide" appears in line 5 of claim 21, it is uncertain which protein or peptide the phrase in line 6 refers to, thus, the metes and bounds of the claim are uncertain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by

Khanna et al (Intl Immunol 1994;6:639-45).

Khanna et al teach a minigene expression vector (nucleic acid construct) comprising an antigen-coding region encoding an EBV CTL epitope (antigenic peptide), linked to an endoplasmic reticulum translocation signal sequence (sorting signal sequence), which acts to direct intracellular transport of the antigenic peptide into the ER (e.g. abstract). *Khanna et al* go on to teach that tumor antigens are often weak antigens, the disclosed construct promoted antigen presentation and could be used as a design strategy for activating specific CTL response to tumors *in vivo* (left column, page 644). Therefore, *Khanna et al* anticipate the instant claim.

It is noted the claim limitation such as "a vaccine for genetic immunization" does not carry patentable weight in the determination of anticipation for the claimed products, because it merely states the intended use of the product.

Applicants are reminded that that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand-alone. The MPEP states, "in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02).

Claims 21, 22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by *Urban et al* (US 5,827,516).

Urban et al teach a nucleic acid construct encoding a antigenic protein and optionally include a signal peptide or trafficking sequence that could direct the antigenic peptide to ER, lysosome or an endosome and using such for nucleic acid immunization (paragraph bridging columns 4 & 5), wherein the nucleic acids may be prepared in a pharmaceutically acceptable carrier by encapsulating them in liposomes (column 5, lines 45-47). *Urban et al* also teach the nucleic acids could be cloned into a viral expression vector such as recombinant vaccinia virus (column 12, lines 65-68). Therefore, *Urban et al* anticipate instant claims.

Claims 21, 22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by *Schwartz et al* (US 5,756,264).

Schwartz et al teach a nucleic acid construct encoding a antigenic protein (column 8, lines 59-60) and optionally including a leader sequence that could direct the antigenic peptide to ER, lysosome or an endosome (column 7, lines 45-59, and claim 9), and using such for nucleic acid immunization (column 14, lines 21-39), wherein the nucleic acids may be prepared in a pharmaceutically acceptable carrier such as liposome (paragraph bridging columns 12-13).

Schwartz et al also teach the nucleic acids could be cloned into a viral expression vector (column 14, lines 3-15). Therefore, *Schwartz et al* anticipate instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Schwartz et al* (US 5,756,264), in view of *Johnston et al* (US 6,194,389).

Claim 23 is drawn to a formulation wherein the nucleic acid construct of claimed invention is coated in a colloidal gold particle.

Schwartz et al teach a nucleic acid construct that meets the limitation of claim 21 as discussed under 35 USC § 102. *Schwartz et al* goes on to teach that

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the construct could be administered to a target tissue via particle bombardment (column 12, lines 45-46). *Schwartz et al* do not specify a colloidal gold particle could be used in the particle bombardment procedure.

However, before the instant effective filing date, *Johnston et al* teach the preferred particles used in particle bombardment for nucleic acid delivery is metallic particles, such as gold (column 6, lines 54-64).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the gold particle as taught by *Johnston et al* in the particle bombardment formulation as taught by *Schwartz et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it is within the knowledge of the ordinary skilled in selecting a suitable type of available particles as a nucleic acid carrier. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 9:30 am - 6 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Q. Janice Li
Patent Examiner
Art Unit 1632


October 17, 2003



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